114. By reason of defendants' conduct of directly and indirectly advertising, marketing and promoting Neurontin for the treatment of chronic pain and depression in an unlawful manner, physicians commenced prescribing Neurontin to their patients diagnosed as suffering from chronic pain and depression, frequently at dosages higher than those approved by the FDA.

115. Upon information and belief, the defendant, WARNER-LAMBERT COMPANY, LLC, was indicted in the United States District Court for the District of Massachusetts for violations of 21 U.S.C. §§ 331(a), 331(d), 333(a), 352(f)(1) and 355, and a copy of such criminal information is annexed hereto as Exhibit "A" and incorporated into this complaint by reference.

116. Upon information and belief, on or about the 7th day of June, 2004, the defendant, WARNER-LAMBERT COMPANY LLC, formally pled guilty to all charges contained in the Information.

117. The drug Neurontin was ineffective in the treatment of the causes and symptoms of plaintiff's condition of chronic pain and depression and plaintiff sustained injury and harm by reason of this reliance upon Neurontin to be effective in the treatment as prescribed by her physician of such chronic pain and depression condition.

118. That at all times hereinafter mentioned, plaintiff's decedent was diagnosed by her physician as suffering from chronic pain and depression and was being treated by her physician for such condition.

119. That at all times hereinafter mentioned, upon information and belief, in reliance upon defendants' direct and indirect advertising, marketing and promoting of Neurontion as being safe and effective for the treatment of chronic pain and depression,

plaintiff's decedent's physician prescribed Neurontin to treat plaintiff's decedent's chronic pain and depression.

120. Plaintiff was prescribed and ingested Defendants' neurontin drug products. Thereafter, Plaintiff developed a skin rash, and/or itching, and/or discoloration of the skin, and/or exfoliation of the skin, and/or shedding of hair, and/or shedding of nails, and/or loss of pigmentation of the skin, and/or hives and/or swelling and/or lesions, and/or burns to Plaintiff's body, and/or scarring from said lesions or burns; and/or injuries affecting the bodily mucous membranes, and/or loss or damaged eyesight; and/or permanent damage to internal organs; and/or hypersensitivity, and/or death, and/or Stevens Johnson Syndrome, and/or Toxic Epidermal Necrolysis syndrome causing Plaintiff to require medical treatment for said condition.

121. Defendants never disseminated to patients or the medical community appropriate instructions or measures that a patient should undertake if the early symptoms of SJS and/or TEN develop while using its neurontin drug products in order to reduce the risk of occurrence of these serious conditions.

122. Defendants have had ample opportunity to change their labeling to provide adequate warnings and sufficient warnings on the safe use of neurontin drug products to reduce or avoid the risk of SJS and TEN, but failed to do so.

123. Pursuant to 21 CFR 201.56, 201.57, 314.80 and 314.81, Defendants and their predecessors have a duty under the post-marketing reporting regulations to report any new and significant information that reflected a clinically meaningful change in adverse experience frequency and severity, and specific data and instructions on how to reduce the risks of SJS and TEN in patients taking neurontin drug products.

124. Defendants were required to provide the FDA a narrative discussion in Periodic or Annual reports, along with Increased Frequency reports and information about overall safety information regarding serious skin reactions associated with neurontin drug products, but failed to provide this information Federal regulations also require that this information, should be provided to the FDA, and to explain what further actions the applicant planned to take to address safety issues in its product labeling, or to add new warnings about serious adverse events.[1]

125. Defendants are also required to provide adequate warnings in the WARNINGS section of the prescribing information to physicians about the risks of serious, life-threatening reaction associated with its neurontin drug products, and that a causal relationship need not be established.

126. The label for Defendants' neurontin drug products, known as the "Package Insert" was developed by the Defendants and accompanied all neurontin prescription drug products and/or samples. By federal law, the labeling is to include accurate information concerning a drug's active and inactive ingredients, clinical pharmacology, indications, usage, contraindications, warnings, precautions and side effects.

127. Defendants failed to fully, truthfully and accurately communicate the risks of Defendants' neurontin drug products and as a result intentionally and fraudulently mislead the medical community, physicians, Plaintiff's physician and Plaintiff about the risks of severe side effects described herein, including but not limited to SJS and TENS associated with the use of the drug.

[1] Guidance for Industry: Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines, March **(2001).**

128. Defendants caused their neurontin drug product package inserts to be disseminated to Plaintiff's physicians and other members of the medical community. Defendants' neurontin package inserts minimized the risk of a severe cutaneous reactions and severe side effects described herein, including but not limited to Stevens Johnson Syndrome and TENS, despite available literature that Defendants should have reported evidencing a statistically significant higher risk for such reactions.

129. Defendants fraudulently and aggressively promoted neurontin drug products to physicians for use in patients, such as Plaintiff, through medical journal advertisements, use of mass mailings, and direct communications from the Defendants sales force, as well as other promotional materials including package inserts, physician desk reference, monographs and patient brochures as these materials downplayed the significance of the adverse effects of neurontin drug products and the risk of SJS, TENS and severe cutaneous reactions.

130. Defendants failed to advise the Plaintiff' physicians and the medical community of the true and accurate risks and regularly represented in advertising and promotional messages the risk same associated with exposure to Defendants' neurontin drug products was minimal when in fact it was significantly greater.

131. The Defendants' neurontin drug products were defective due to inadequate pre-marketing and post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of injury associated with the drug, Defendants failed to provide adequate warnings to Plaintiff's physicians, Plaintiff, and the medical community who prescribed said drug, and to their patients who were the ultimate consumers of the drug. Yet despite Defendants inadequate post-marketing warnings and

instructions to said persons Defendants continued to aggressively promote the drug thereby making Defendants strictly liable for failure to warn.

132. Plaintiff's and their physicians were not aware of information different from or contrary to the inaccurate, misleading, materially incomplete, false and/or otherwise inadequate information disseminated by Defendants concerning the safety and efficacy of neurontin drug products.

133. Defendants provided misleading information about the true risks associated with the use of said neurontin drug products to the medical community, Plaintiff's physician, and Plaintiff (and other foreseeable users similarly situated).

134. Plaintiff used Defendants' neurontin drug products without substantial change in condition of said drug products between the time of design and manufacture of the drug products and the time of use.

135. Plaintiff's serious and permanent injuries, came about as a foreseeable and proximate result of the Defendants' dissemination of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information concerning the effects of exposure and ingestion of the drug to the medical community, physicians, Plaintiff's physician, Plaintiff and other foreseeable users of the drug.

136. Plaintiff have experienced and will continue to experience medical and related expenses, loss of ability to provide household services, disfigurement, disability, pain and suffering, psychological injury and other injuries and damages due to the injuries suffered caused by the ingestion of Defendants' neurontin drug products.

IV.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

137. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through failing to disclose a known defect to Plaintiff's physicians and/or Plaintiff, and misrepresenting their drug as safe for its intended use, actively concealed from said individuals the true risks associated with the use of their neurontin drug products.

138. As a result of Defendants' actions, Plaintiff and Plaintiff's physicians were unaware, and could not reasonably known or have learned through reasonable diligence of the manufacturing defect and have been exposed to the risks alleged herein and that those risks were a direct and proximate result of Defendants' acts and omissions.

139. Furthermore, Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the defective nature of their neurontin drug products. Defendants were under a duty to disclose the true character, quality, and nature of said drugs because this was non-public information over which the Defendants have, and continue to have, exclusive control, and because Defendants knew that this information was not available to the Plaintiff or their physicians. In addition, the Defendants are estopped from relying on any statute of limitations because of their concealment of these facts.

140. Plaintiff had no knowledge that Defendants was engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by the Defendants, the Plaintiff could not have reasonably discovered the wrongdoing at any time prior to the commencement of this action. Plaintiff, nor Plaintiff's physicians, could have possibly determined the nature, extent and identity of related health risks dealing with the manufacturing defect of Defendants' drug and

reasonably relied on Defendants' to disseminate truthful and accurate safety and efficacy information about its drug and warn of the side effects complained of herein.

V.

ALLEGATIONS

141. At all relevant times hereto, Defendants did not investigate the accuracy of the neurontin drug product labeling.

142. Defendants were negligent in failing to report published articles and overwhelming scientific evidence of increased risks of severe side effects described herein including SJS and TEN associated with neurontin therapy to the FDA, healthcare providers and patients, including Plaintiff, in the U.S.

143. FDA regulations required Defendants to report literature, papers; and, to undertake action to add new warnings to the package insert for neurontin drug products, and to report any foreign regulatory actions that included new warnings or new safety information for the drug.

144. At all relevant times hereto, Defendants did not review the medical literature for its neurontin drug products.

145. Defendants are under a duty to ensure that their neurontin drug product labels are accurate.

146. Under the Code of Federal Regulations, Defendants, have a duty to ensure its neurontin warnings to the medical community were accurate and adequate; have a duty to conduct post market safety surveillance; to review all adverse drug event information, and to report any information bearing on the risk and/or prevalence of side effects caused by neurontin drug products, the medical community, Plaintiff's physicians,

Plaintiff and other foreseeable users.

147. Under federal regulations if Defendants discover information in the course of the fulfillment of its duties as outlined above, Defendants must report that information to the medical community, Plaintiff's physicians, Plaintiff and other foreseeable users of neurontin therapy to ensure that its warnings are continually accurate and adequate.

148. Defendants breached its duty to the medical community, Plaintiff's physicians, Plaintiff, and other foreseeable users similarly situated because it failed to provide warnings to said persons, which were accurate and adequate.

149. Defendants breached their duty to the medical community, Plaintiff's physicians, Plaintiff, and other foreseeable users similarly situated because it failed to conduct post market safety surveillance of the drug, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of neurontin drug products.

150. Defendants breached their duty to the medical community, Plaintiff's physicians, Plaintiff, and other foreseeable users similarly situated because Defendants failed to review all adverse drug event information (ADE), and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by neurontin drug products to said persons and other foreseeable users.

151. Defendants breached their duty to the medical community, Plaintiff's physicians, Plaintiff, and other foreseeable users similarly situated because it failed to periodically review all medical literature and failed to report any significant data concerning severe side effects as described herein, including but not limited to SJS and

TENS, *regardless of the degree of significance*, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of neurontin drug products.

152. If a drug company learns of side effects, risks or misleading and inaccurate information in the neurontin drug product label, it must request and/or submit labeling revisions for said drug, under the FDA schema.

153. Defendants knew or should have known about the side effects, risks, misleading and inaccurate information contained in their neurontin drug product labels and knowingly and intentionally withheld that information and or failed to report that information to the medical community, physicians, Plaintiff, Plaintiff's physicians and other foreseeable users.

154. At all times material hereto, Defendants were aware of the serious side effects described herein which were caused by their neurontin drug products and failed to fulfill its obligation to report and divulge said side effects, and in doing so, mislead the medical community, physicians, Plaintiff's physicians, Plaintiff and other foreseeable users about the safety of neurontin drug products.

155. At all times material hereto, Defendants knew or should have known that physicians and Plaintiff were unaware of or did not fully appreciate the seriousness of the risks associated with use of neurontin drug products.

156. Defendants knew or should have known that the package inserts and the Physician Desk Reference monographs for their neurontin drug products did not adequately inform physicians about the risks of severe side effects described herein, and/or SJS or TENS associated with the drug; yet, said Defendants failed to communicate said information to the medical community, Plaintiff's physicians, Plaintiff or other

foreseeable users alike, and in doing so, mislead the medical community, physicians, Plaintiff's physicians, Plaintiff and other foreseeable users about the safety of this drug.

157. Defendants knew, or should have known through the exercise of reasonable care, that the package insert for the drug substantially understated the prevalence of the risk of severe side effects described herein.

158. Defendants willfully and in wanton disregard of the rights of Plaintiff, failed to disclose and communicate material safety information regarding the risks of this drug to the medical community, Plaintiff's physicians, Plaintiff and other like foreseeable users, knowing that such failure would result in serious injury to patients who were prescribed neurontin drug products by a physician and were not aware of the risk of severe skin reactions, SJS and TENS.

159. Defendants falsely and fraudulently represented to physicians, Plaintiff physicians, and to foreseeable users, including Plaintiff, that neurontin drug therapy was safe and that permanent and severe side effects described herein, SJS and TENS were rare and/or infrequent.

160. Defendants did not disclose or warn physicians about the actual prevalence of known side effects of neurontin therapy when the drug is used as marketed by Defendants, or when used in patients such as of Plaintiff, all of which were foreseeable.

161. At the time Defendants made the above-described representations, Plaintiff and Plaintiff's physicians were ignorant of the falsity of the representations and reasonably believed them to be true.

162. Plaintiff's serious and permanent injuries, as described above, came about

as a foreseeable and proximate result of Defendants' failure to correct false and misleading information it disseminated to physicians, which contained inaccurate, misleading, materially incomplete, false and otherwise inadequate information concerning the efficacy, safety and potential side effects of the drug.

163. In doing the acts alleged in this Complaint, Defendants acted with oppression, fraud, and malice and Plaintiff is therefore entitled to punitive damages to deter Defendants and others from engaging in similar conduct in the future.

164. As a proximate result of the fraud and deceit of Defendants, Plaintiff sustained the injuries and damages as described in this Complaint.

165. Defendants have an absolute duty to disclose the true facts regarding the safety of neurontin drug products to the medical community, to physicians and their patients, pharmacists, and the generic neurontin drug industry, which it negligently and/or intentionally failed to do.

166. Defendants have a duty to ensure that it had a reasonable basis for making the representations regarding the safety; efficacy, risks and benefits of the drug were accurate which it negligently and/or intentionally failed to do.

167. Plaintiff would not have suffered Plaintiff's injuries but for the above misrepresentations or omissions of Defendants.

168. Defendants' misrepresentations or omissions were a cause in fact and a proximate cause of Plaintiff's damages.

169. At all times mentioned in this Complaint, the Defendants had a duty to truthfully, accurately and fully disclose information and data to Plaintiff that the risks of severe side effects described herein, including, SJS and TENS, clearly outweighed the

utility of the drug or its therapeutic benefits to patients.

170. The Defendants were negligent, and breached their duty owed to the medical community, Physicians, Plaintiff's physicians, Plaintiff and other like foreseeable users, with respect to the drug in one or more of the following respects:

(a) Despite knowledge of hazards and knowledge that the drug was frequently prescribed for the use of Plaintiff and other consumers of neurontin, Defendants failed to accompany the drug with adequate warnings and instructions regarding the adverse side effects associated with the use of the drug; and

(b) Defendants failed to perform adequate testing on the drug; and

(c) Despite knowledge of hazards, Defendants failed to conduct adequate post-marketing surveillance to determine the safety of the drug; and

(d) Despite knowledge of hazards, Defendants failed to adequately warn Plaintiff's physicians or Plaintiff that the use of the drug could result in serious side effects, including severe skin reactions, SJS and TENS; and

(e) Despite the fact that the Defendants knew or should have known that the drug caused unreasonably dangerous side effects, Defendants failed to adequately disclose the known or knowable risks associated with the drug and willfully and deliberately failed to adequately disclose these risks, and in doing so, acted with a conscious disregard of Plaintiff's safety or welfare and the safety and welfare of other foreseeable users.

(f) Despite the fact that the Defendants knew or should have known that neurontin drug products caused unreasonably an increased risk of severe skin reactions Defendants failed to adequately disclose the known or knowable risks associated with the drug and willfully and deliberately failed to adequately disclose these risks, and in doing so, acted with a conscious disregard of Plaintiff's safety or welfare and the safety and welfare of other like foreseeable users of the drug.

171. As a result of the negligence of the Defendants and its willful and wanton misconduct, Defendants' neurontin drug products were prescribed to Plaintiff for their

respective use; were used as prescribed; thereby, causing Plaintiff to sustain reasonably foreseeable serious and permanent damages and injuries as alleged in this complaint.

172. The negligence and the willful and wanton misconduct of the Defendants was a proximate cause of Plaintiff's harm and injuries that Plaintiff suffered and will continue to suffer.

173. At all times mentioned in this Complaint, the drug was defective and/or unreasonably dangerous to Plaintiff and other foreseeable users at the time it left the control of the Defendants.

174. The drug was "defective" and "unreasonably dangerous" when it was promoted and entered into the stream of commerce and was received by Plaintiff, in one or more of the following respects:

(a) At the time the drug left the control of the Defendants it was defective and unreasonably dangerous due to a failure to contain adequate warnings or instructions, or, in the alternative, because it was designed in a defective manner, or, in the alternative, because the drug breached an express warranty or failed to conform to other expressed factual representations upon which Plaintiff's physicians justifiably relied, or because it breached an implied warranty, all of which proximately caused the damages for which Plaintiff seeks recovery herein.

(b) Defendants' neurontin drug products were not reasonably safe as designed, taking into account the foreseeable risks involved in its use at the time the drugs left the possession of the Defendants, and that such risks clearly outweighed the utility of neurontin therapy or its therapeutic benefits.

(c) At the time the drug left the control of the Defendants the drug possessed a dangerous characteristic that may cause damage and it was not reasonably safe due to inadequate or defective warnings or instructions that were known or reasonably scientifically knowable at the time the drug left the possession of the Defendants. Specifically, although the Defendants was well aware that the drug products could potentially cause severe side effects described herein, SJS and TENS, warnings of such adverse health conditions

were either not included on the package insert for the drug and/or the warnings were inadequate to inform reasonably prudent physicians and foreseeable users of the risks. The Defendants failed to use reasonable care to provide an adequate warning of these dangerous characteristics to handlers and users of the drug.

(d) The Defendants' warnings or instructions were not of a nature that a reasonably prudent drug company in the same or similar circumstances would have provided with respect to the danger. There were no warnings or instructions that communicate sufficient information on the dangers and safe use of the drug taking into account the characteristics of the neurontin, and/or the ordinary knowledge common to the physician who prescribes and the consumer who purchases the drug, such as the Plaintiff.

(e) The drugs manufactured and supplied by the Defendants were further defective due to inadequate post-marketing warning or instruction because, after the Defendants knew or should have known of the risks of injury from neurontin drug products associated with the use as commonly prescribed, Defendants failed to promptly respond to and adequately warn about severe skin reactions, SJS and TENS to foreseeable users.

(f) The drugs as manufactured and supplied by the Defendants were further defective due to inadequate post-marketing warning or instruction because, after the Defendants knew or should have known of the risks of injury from the drugs associated with the use as commonly prescribed, Defendants failed to promptly respond to and adequately warn about an increased risk as reported in the medical literature for severe skin reactions, SJS and TENS posed to patients, who were foreseeable users of the drug products.

175. The Defendants knew, or in light of reasonably available scientific knowledge should have known, about the danger that caused the injuries for which Plaintiff seeks recovery.

176. A reasonably competent physician who prescribed the drug and a reasonably competent Plaintiff who consumed the drug would not realize its dangerous condition.

177. The reasonably foreseeable use of Defendants' neurontin drug products

involved substantial dangers not readily recognizable by Plaintiff's physicians, who acted as ordinary, reasonable and prudent physicians would, when prescribing the drug to ordinary, reasonable and prudent patients, like Plaintiff.

178. The Defendants knew that Defendants' neurontin drug products prescribed by physicians and used by Plaintiff was not properly prepared nor accompanied by adequate warnings of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

179. Plaintiff and Plaintiff's physicians did not know, nor had reason to know, at the time of the use of the drug, or at any time prior to its use, of the existence of the above-described defects and inadequate warnings.

180. These defects caused serious injuries to Plaintiff when the drug was used in its intended and foreseeable manner, and in the manner recommended by the Defendants and/or in a non-intended manner that was reasonably foreseeable.

181. Defendants knew that its warranties regarding safety for the use, would be relied upon by ordinary, reasonable and prudent physicians who would share that information with other physicians in their community and that eventually physicians would come to rely on Defendants' express warranties concerning the safety of the drug.

182. Defendants' express warranties about the safety of the drug were false and intentionally and/or negligently misleading.

183. Defendants also knew that the risks of potentially severe side effects described herein, including SJS and TENS when using the drug is much greater than most physicians realized. By failing to give adequate warnings about the properties of the drug and the risk of the use that is associated with those properties, the Defendants

breached implied warranties of merchantability and fitness for the ordinary use of their neurontin drug products.

184. At all times mentioned in this Complaint, the Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied and sold their neurontin drug products and prior to the time the drugs were used by Plaintiff, the Defendants impliedly warranted to Plaintiff and to Plaintiff's physicians that the drugs were of merchantable quality and safe and fit for the use for which the drugs were intended.

185. Plaintiff relied on the skill and judgment of the Defendants in using the drugs.

186. Defendants' neurontin drug products were unsafe and unfit for intended use; were not of merchantable quality, as warranted by the Defendants, in that the drugs had very dangerous propensities when put to its intended use and would cause severe injury to the user.

187. Defendants' neurontin drug products were not properly prepared nor accompanied by adequate warnings concerning the drugs dangerous propensities that were either known or reasonably scientifically knowable by the Defendants at the time of distribution. As a result, the drug proximately caused Plaintiff to sustain damages and injuries as alleged in this Complaint.

188. By virtue of Defendants' acts and omissions, Defendants are liable to Plaintiff because Defendants' acts and omissions have proximately caused Plaintiff to suffer permanent injuries.

189. Plaintiff used Defendants' neurontin drug products, which were provided

to them, respectively, in a condition that was substantially the same as the condition in which the drugs were manufactured and sold.

190. Defendants through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and their physicians the true and significant risks associated with taking their neurontin drug products; and thus, the running of any applicable statute of limitations has been tolled by reason of Defendants' fraudulent concealment.

191. As a result of Defendants' actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

192. As a direct and proximate result of the acts and omissions of Defendants, the Plaintiff were prevented from pursuing her normal activities and employment, has experienced severe pain and suffering and mental anguish, and has been deprived of her ordinary pursuits and enjoyments of life.

193. Equity dictates that this Court provide the Plaintiff a remedy that provides Plaintiff with sufficient information and medical monitoring appropriate for Plaintiff to make informed decisions related to Plaintiff's physical well-being. Absent such notice Plaintiff will be irreparably harmed.

194. Plaintiff is entitled to any procedural protections deemed necessary and appropriate to protect Plaintiff's legal interests.

195. Based upon the allegations set forth herein, the Defendants knew of facts

that created a high degree of risk of physical harm to the Plaintiff and yet the Defendants deliberately proceeded to act in conscious disregard or indifference to that risk, and therefore an award of punitive damages is warranted.

196. Plaintiff is entitled to recovery of an award for the injuries caused by the Defendants.

197. As a direct and proximate result of the aforesaid acts of and/or omissions by the Defendants, Plaintiff, has:

(a) Suffered severe and permanent injuries, and will endure same for the remainder of Plaintiff's life;

(b) Suffered physical impairment and disfigurement; and

(c) Suffered physical pain and suffering;

(d) Suffered mental pain and suffering; and

(e) Suffered from loss of enjoyment of life; and

(f) Incurred and will continue to incur various sums of money for past, present and future medical expenses associated with monitoring and treating Plaintiff's injuries; and

(g) Incurred attorney's fees and expenses of litigation related to this action.

198. Defendants' actions were intentional, willful, wanton, oppressive, malicious, and reckless, evidencing such an entire want of care as to raise the presumption of a conscious indifference to the consequences and acted only out of self interest and personal gain and evidenced a specific intent to cause harm to Plaintiff.

COUNT 1

STRICT PRODUCTS LIABILITY

199. Plaintiff repeats, reiterates, and re-alleges each and every allegation

contained in this Complaint with the same force and effect as if fully set forth.

200. At all relevant times the Defendants were engaged in the business of manufacturing, designing, testing, marketing, promoting, distributing, and/or selling neurontin drug products.

201. Defendants, developed, marketed and distributed neurontin drug products to the general public even after learning of the design and manufacturing defects that threatened the intended use of the drug.

202. Defendants' neurontin drug products were defective and unreasonably dangerous and were expected to and did reach Plaintiff without substantial change.

203. At all times mentioned in this Complaint, Defendants' neurontin drug products were defective and/or unreasonably dangerous to Plaintiff and other foreseeable users at the time the drugs left the control of the Defendants.

204. Defendants knew or should have known through testing, adverse event reporting, or otherwise, that the drugs created a high risk of bodily injury and serious harm.

205. The dangerous propensities of Defendants' neurontin drug products were known or scientifically knowable, through appropriate research and testing, to the Defendants at the time said Defendants distributed, supplied, or sold the drugs, and not known to ordinary physicians who would be expected to prescribe the drugs for their patients.

206. Defendants' neurontin drug products, as distributed, were defective and unreasonably dangerous inasmuch as the drugs were not accompanied by warnings and instructions that were appropriate and adequate to render the drugs reasonably safe for their ordinary, intended, and reasonably foreseeable uses, in particular the common, foreseeable,

and intended use of the drugs.

207. Prior to the manufacturing, sale and distribution of said drug products, Defendants knew that their neurontin drug products were in a defective condition as previously described, and knew that those who were prescribed and took the same would experience, and did experience, severe physical, mental and emotional injuries.

208. Defendants had prior notice and knowledge from several sources, prior to the date of dispensing of said drug products to Plaintiff, that their neurontin drug products presented a substantial and unreasonable risk of harm to the public, including Plaintiff, and as such said consumers of said drug were unreasonably subjected to risk of injury or death from the consumption of said drug products.

209. Despite such knowledge, Defendants for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to warn of the extreme risk of physical injury occasioned by said defects inherent in said neurontin drug products.

210. In order to advance Defendant's own pecuniary interests, Defendants intentionally proceeded with the manufacturing, the sale and distribution, and marketing of neurontin drug products with knowledge that consumers would be exposed to serious danger.

211. Defendants' neurontin drug products were "defective" and "unreasonably dangerous" when the drugs initially were patented, and subsequently when the drugs were promoted and entered into the stream of commerce and were received by Plaintiff, in one or more of the following respects:

(a) At the time the drug left the control of the Defendants it was defective and unreasonably dangerous due to a failure to contain adequate warnings or instructions, or, in the alternative, because it was designed in a defective manner, or, in the alternative, because

the drug breached an express warranty or failed to conform to other expressed factual representations upon which Plaintiff's physicians justifiably relied, or because it breached an implied warranty, all of which proximately caused the damages for which Plaintiff seek recovery herein.

(b) Defendants' neurontin drug products were not reasonably safe as designed, taking into account the foreseeable risks involved in its use at the time the drugs left the possession of the Defendants, and that such risks clearly outweighed the utility of neurontin therapy or its therapeutic benefits.

(c) At the time the drug left the control of the Defendants the drug possessed a dangerous characteristic that may cause damage and it was not reasonably safe due to inadequate or defective warnings or instructions that were known or reasonably scientifically knowable at the time the drug left the possession of the Defendants. Specifically, although the Defendants was well aware that the drug products could potentially cause severe side effects described herein, SJS and TENS, warnings of such adverse health conditions were either not included on the package insert for the drug and/or the warnings were inadequate to inform reasonably prudent physicians and foreseeable users of the risks. The Defendants failed to use reasonable care to provide an adequate warning of these dangerous characteristics to handlers and users of the drug.

(d) The Defendants' warnings or instructions were not of a nature that a reasonably prudent drug company in the same or similar circumstances would have provided with respect to the danger. There were no warnings or instructions that communicate sufficient information on the dangers and safe use of the drug taking into account the characteristics of the neurontin, and/or the ordinary knowledge common to the physician who prescribes and the consumer who purchases the drug, such as the Plaintiff.

(e) The drugs manufactured and supplied by the Defendants were further defective due to inadequate post-marketing warning or instruction because, after the Defendants knew or should have known of the risks of injury from neurontin drug products associated with the use as commonly prescribed, Defendants failed to promptly respond to and adequately warn about severe skin reactions, SJS and TENS to foreseeable users.

(f) The drugs as manufactured and supplied by the Defendants were further defective due to inadequate post-marketing warning or instruction because, after the Defendants knew or should have

known of the risks of injury from the drugs associated with the use as commonly prescribed, Defendants failed to promptly respond to and adequately warn about an increased risk as reported in the medical literature for severe skin reactions, SJS and TENS posed to patients, who were foreseeable users of the drug products.

212. The Defendants knew, or in light of reasonably available scientific knowledge should have known, about the danger that caused the injuries herein.

213. The Defendants knew or in light of reasonably available scientific knowledge should have known about the danger associated with use of the drug that caused the damages herein.

214. The reasonably foreseeable use of the drugs involved substantial dangers not readily recognizable by the ordinary physician who prescribed the drug or the patient, including Plaintiff, who consumed Defendants' neurontin drug products.

215. The Defendants knew that their neurontin drug products were to be prescribed by physicians and used by consumers without inspection for defects in the product or in any of its components or ingredients and that the drugs were not properly prepared nor accompanied by adequate warnings of the dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

216. Plaintiff and Plaintiff's physicians did not know, nor had reason to know, at the time of the use of Defendants' neurontin drug products, or at any time prior to its use, of the existence of the above-described defects and inadequate warnings.

217. These defects caused serious injuries to Plaintiff when the drugs were used in its intended and foreseeable manner, and in the manner recommended by the Defendants and/or in a non-intended manner that was reasonably foreseeable.

COUNT 2

BREACH OF EXPRESS WARRANTY

218. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth.

219. Defendants' expressly warranted to Plaintiff that Defendants' neurontin drug products were safe and effective.

220. In response to these promises and express statements, Plaintiff and Plaintiff's physicians relied on such affirmations and warranties.

221. Defendants' neurontin drug products do not conform to those express representations in light of recently discovered disclosures and information previously withheld by Defendants. Defendants' express warranty through its false statements failed to disclose design, manufacturing and safety defects inherent in the drug.

222. Defendants breached its warranties of the drug by continuing sales and marketing campaigns highlighting the safety of its neurontin drug products, while it knew of the design, manufacturing and safety defects and the risk of contracting severe skin reactions, serious side effects as described herein, including SJS and/or TENS.

223. As a direct and proximate result of Defendants' breach of its express warranty, Plaintiff suffered bodily and mental injury, harm, other compensable injury and economic losses, compensable through this Court.

COUNT 3

NEGLIGENCE

224. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

225. Defendants had a duty to exercise the care of an expert in all aspects of the

formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, and sale of their neurontin drug products to ensure the safety of the drug products and to ensure that the consuming public, including the Plaintiff and Plaintiff's physicians and agents, obtained accurate information and instructions for the use of said drugs.

226. As a direct and proximate cause of Defendants' conduct, Plaintiff has suffered and will continue to suffer injury, harm, and economic loss as alleged herein, including permanent and substantial physical injuries, and expenses attributable to said injuries.

227. Defendants owed a duty toward foreseeable users of their neurontin drug products to exercise reasonable care to ensure that the neurontin drugs it manufactured and/or distributed were reasonably safe for ordinary and intended uses, and specifically, *inter alia*, to ensure through adequate testing, labeling, and otherwise, that physicians who would be likely to prescribe the products for their patients' use were adequately informed as to the potential effects of using the products in ordinary and foreseeable ways, in particular the risks of a severe cutaneous reactions, SJS and/or TENS, inherent in such use.

228. Defendants failed to exercise reasonable care in testing the drug for side effects in ordinary and foreseeable users; and failed to disseminate to physicians information concerning the effects of the drugs, which was accurate, not misleading, and otherwise adequate to enable physicians to make informed choices concerning the use of Defendants' neurontin drug products.

229. Defendants failed to exercise ordinary care in the manufacture, sale, testing, marketing, quality, assurance, quality control and/or distribution of the drugs into the stream

of interstate commerce in that Defendants knew or should have known that their neurontin drug products created a foreseeable high risk of unreasonable, dangerous side effects and health hazards.

230. The dangerous propensities of Defendants' neurontin drug products as referenced above, were known or scientifically knowable, through appropriate research and testing, to the Defendants at the time it distributed, supplied, or sold the products, and not known to ordinary physicians who would be expected to prescribe said drugs for Plaintiff and other patients, similarly situated.

231. The information the Defendants disseminated to physicians concerning neurontin drug products was, in fact, inaccurate, misleading, and otherwise inadequate, as described above.

232. As a proximate result, Plaintiff suffered grievous bodily injuries and consequent economic and other losses when Plaintiff ingested said drug products, which had been developed, manufactured, labeled, marketed, distributed, promoted and/or sold, either directly or indirectly, by Defendants through third parties or related entities.

233. The Defendants was negligent, and breached duties owed to Plaintiff with respect to their neurontin drug products in one or more of the following respects:

(a) Despite knowledge of hazards and knowledge that the product was frequently prescribed for the use, Defendants failed to accompany the product with adequate warnings and instructions regarding the adverse and long lasting side effects associated with the use of the drugs;

(b) Defendants failed to conduct adequate testing; and

(c) Despite knowledge of hazards, Defendants failed to conduct adequate post-marketing surveillance to determine the safety of the product; and